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UCLA COMPREHENSIVE
SPINE CENTER

UNIVERSITY SPINE ASSOCIATES

Edgar G. Dawson, M.D.
Clinical Professor,
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UCLA School of Medicine

November 30, 1999

Document Managed Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville MD 20852

RE: Docket No.: 97N-484S

To Whom It May Concern:

I have read the September 30, 1999 issue of the Federal Register and am appalled that the FDA would try and regulate devices that are already in active clinical use and have been proven to be safe and effective. To take allograft material which is used all the time and have to go back to satisfying your premarket requirements would be enormously expensive, a waste of time and increase the financial burden on an already crippled health care delivery system.

I plead with you to please change your attitude toward these devices and to allow us to continue to use them for the benefit of patients without the increased cost necessary to satisfy a bureaucratic decision.

Sincerely,



Edgar G. Dawson, M.D.
University Spine Associates
Clinical Professor,
Orthopaedic Surgery
UCLA School of Medicine

EGD:MTSS/th trans: 12/2/99

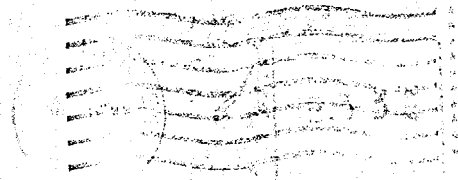
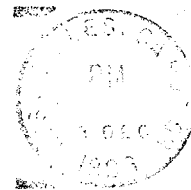
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